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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NIKOLAI & MERSEREAU, P.A.
900 SECOND AVENUE SOUTH
SUITE 820
MINNEAPOLIS, MN 55402

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,628	ANDERSON ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12 and 16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12 and 16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed on 03/26/2008. Upon entering the amendment, the claim 10 has been amended and claims 11 and 13-15 has been cancelled. Accordingly, claims 10, 12 and 16-24 are pending and presented for examination.

Response to Arguments

2. Applicant's arguments filed on 03/26/2008 have been fully considered but they are not persuasive. The 112(2) rejection is withdrawn in view of amendments to claims. However, 103(a) rejection Marcenyac et al is maintained and made it **FINAL**.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10, 12 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcenyac et al (US 2004/0146547).

With respect to claims 10, 12 and 16-24, Marcenyac et al discloses an article (a transdermal patch) includes a reservoir housing a dye and/or medicament inactivating agent in communication with the reservoir that is released when the reservoir is opened or revealed (see 0009). And further, the article may include a pocket having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed by a flap covered at least in part by a permanent pressure and/or heat sensitive adhesive (see 0014). And also the disposing of a transdermal patch includes placing a transdermal patch within the article, sealing the patch within a pocket of the article, such that the article releases the detection material and/or inactivating agent when the reservoir is opened and thus the article prevents of hinders misuse of the active agent contained in the transdermal dosage form (see 0022). And further, article includes a medicament layer having a transfer side and an opposite side; a first adhesive contained in the medicament layer; an outer layer having a medicament layer facing side and an opposite side, the medicament layer being joined to outer layer to form one or more closed material reservoir; and a detection material and/or medicament-inactivator in the reservoir which is released when the reservoir is opened (see 0023-0027). And also, discloses a method of disposing of a transdermal patch comprising: placing said transdermal patch on said opposite side of said inner layer of an article and contacting said adhesive covering at least a portion of said opposite side of said inner layer with a different portion of said

opposite side of said inner layer to form a sealed pocket enclosing said transdermal patch (see 0044 and 0045). And medicament layer contains an opiate e.g. fentanyl; the inactivating agent include the rat or human mu-opioid receptor; opioid-neutralising antibodies; narcotic antagonists such as naloxone, naltrexne and nalmedrne; dysphoric or irritating agents such as scopolamine, ketoamine, artropine or mustard oils or any combinations thereof (see 0112 and 0114). And in practice, if the active agent in a transdermal patch to be disposed of by placing it in the present article were an opioid, the inactivating agent renders the active agent unavailable through inactivation, such as for example chemical inactivation or alteration of the receptor binding site of the active agent; biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like; or something similar thereto. One or more inactivating agent(s) may be used (see 0099). And further discloses that it is known in prior art (US 5,804,215) to Cubbage et al. relates to disposal system for a transdermal patch comprising a pouch for transport of the patch and disposal system encapsulates a trasndermal patch and prevents access to it.

Marcenyac et al. meets all the limitations of instant claims except that it uses different anti-abuse substance. However, Marcenyac et al. teaches use of various anti-abuse substances directly related to effective in preventing abuse, particularly if the active agent is a narcotic or a controlled substance (e.g. used dosage forms containing excess or unused opioids which may be tampered with by chewing or extraction by a drug abuser). Since the inactivating agents is directly related to anti-abuse substance,

and the prior art teaches the same subject matter (disposable of transdermal patch containing residual or unused opioid in a separate pouch) by similar process, it is examiner's position that, in the absence of evidence to the contrary, a suitable specific anti-abuse substance is also either anticipated by Marcenyac, or obviously provided by practicing the invention of prior art. It should be noted that where claimed and prior art products are shown to be identical or substantially identical in composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See MPEP § 2112.01

Applicant's arguments filed on 03/26/2008 have been fully considered but they are not persuasive.

Applicant asserts that Marcenyac et al reference is not of good date.

This is not found persuasive since the Marcenyac reference is good as 102 (e) date which claims a priority date to provisional application filed on May 22, 2001.

Applicant also asserts that marcenyac does not teach or suggest the use of a binding or adsorption agent that prevents subsequent solvent extraction of said abusable substance of interest.

This is not found persuasive, since the reference teaches various inactivating agent, when contacted with or a medicament or active agent to be placed in the article, renders the active agent unavailable through inactivation, such as for e.g. if the active agent in a transdermal patch to be disposed of by placing it in the present article were an opioid, the inactivating agent could be a chemical or denaturing agent that would alter residual opioid molecules in the dosage form and make them inactive. The

inactivating agent could be an opioid receptor that would bind the residual opioid into an insoluble ligand-receptor complex, or biounavailability; physical unavailability; loss of appeal of the active agent to the abuser, such as for example, an inactivating agent which creates an intolerably bad taste or an intolerable reaction such as extreme nausea or the like. Further the inactivating agent may be released when the dosage form is handled in a particular manner, squeezed with sufficient force, or if the dosage form is abused, such as for example, is chewed, soaked, subjected to extraction. Thus, this article could be used, for example, to inactivate any residual active agent when the dosage form is discarded. It is well established that the claims are given the broadest reasonable interpretation during examination in light of the supporting disclosure as it would be interpreted by one of ordinary skill in the art, In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023,1027-28 (Fed. Cir. 1997); *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359,1364, [70 USPQ2d 1827] (Fed. Cir. 2004). Further, it has been held that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). In the present case, the inactivating agents disclosed by the prior art reads on the claimed binding or adsorption agent, in absence of claiming specific characteristics of the binding or adsorption agent.

Applicants further, argues that Marcenyac does not disclose a self-extracting separator membrane which is removed automatically upon the removal of the patch from the skin.

This is not found persuasive, since the reference teaches the article that includes a pocket having a sealable opening and formed between first and second portions of the opposite side of the inner layer, wherein the opening is optionally sealed by a flap covered a least in part by a permanent pressure and/or heat sensitive adhesive. And further, the article may also include a peelable release layer covering the adhesive. Since the reference teaches the same desired function of safely disposing the transderaml patch, and the article comprising an outer layer and an inner layer which are joined by an adhesive covering a first portion of the inner layer, and the inner and outer layers of the reference is capable of performing the same function, then it meets the claims. The art as a whole teaches a disposable article to prevent the misuse of a transdermal dosage form for the transdermal delivery of opoids. Obviousness does not require absolute predictability.

Conclusion

1. No claims are allowed at this time.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr